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Industry Representative to the Circulatory System Devices Advisory Panel

Professional Experience:

- Alcon Research, LTD.
- W. L. Gore & Associates, Inc.
- Sulzer Carbomedics Inc

Education:

- University of Oklahoma: BA, MA

Technical Publications and Presentations:

- Chairman, Devices Track, Regulatory Affairs Professional Society (RAPS) Twenty-sixth Annual Conference, Washington, DC, October 2002
- "Pre-clinical testing for aortic endovascular grafts: results of an FDA workshop". Dorothy B. Abel, et al. *Journal of Vascular Surgery,* May 2002; 35:1022-8
- Moderator for the FDA Division of Ophthalmic Devices Breakout Session, AdvaMed Twelfth Annual Device Submissions Workshop, Rockville, MD, June 2002
- Chairman, Devices Track, Regulatory Affairs Professional Society (RAPS) Twenty-fifth Annual Conference, Baltimore, MD, November 2001
- Steering Committee Member, Workshop on Pre-Clinical Testing for Endovascular Grafts, an FDA-sponsored workshop, 31 July-1 August 2001, Gaithersburg, MD.
- Moderator for the FDA Division of Cardiovascular and Respiratory Devices Breakout Session, also presenting "Modular PMAs", AdvaMed Eleventh Annual Device Submissions Workshop, Washington, D.C., 15 June 2001
- "PMA Options", Developing the PMA: A Device Workshop, , Regulatory Affairs Professional Society (RAPS) workshop, San Diego, California, March 5, 2001
- Co-chair "Fundamentals of the Investigational Device Exemption: A Device Workshop", RAPS workshop, San Francisco, California, January 9-10, 2001
- "The Modular PMA", PMA and 510(k) Workshop, Institute for International Research, Marina Del Rey, California, December 11, 2000
- "Advertising and Promotion of Medical Devices", Session moderator, Regulatory Affairs Professional Society (RAPS) Annual Conference, Washington, D.C., October 3, 2000
- "Industry Perspective: PMA Agreement Meetings" AdvaMed Tenth Annual Device Submissions Workshop, Washington, D.C., July 18, 2000
- Chairman, Medical Device Design Controls and Process Validation, Fourth Annual Conference, Institute for International Research, Keynote address: "Management Responsibility", Coronado, California, May 22-24, 2000
- "510(k) Modifications" and "FDA Meetings: Early Collaboration Meetings" Medical Devices Today: Current Issues, RAPS Conference, Alexandria, Virginia, March 14-15, 2000

- "How to Use the 510(k) Modifications Flowchart", Getting on the Market Sooner, HIMA Workshop, Washington, D.C., December 1, 1999
- "Design Transfer", Medical Device Design Controls and Process Validation, Third Annual Conference, Institute for International Research, , San Diego, California, October 27, 1999
- "PMA Early Collaboration Meetings", RAPS Annual Conference, Washington, D.C., October 6, 1999
- "Industry Perspective: Managing Medical Device Changes", HIMA Device Submissions Workshop, Washington, D.C., July 28, 1999
- "New Canadian Regulations", Session moderator, Regulatory Affairs Professional Society (RAPS) Annual Conference, Washington, D.C., October 28, 1998
- "A Model PMA Shell for a Prosthetic Heart Valve" Presentation of a modular PMA model at the HIMA Device Submissions Workshop, Washington, D.C., July 29, 1998
- Co-chair, "The Quality System Regulation", RAPS workshop, Dallas, Texas, June 8-9, 1998
- "A Model Antibiotic Prosthetic Heart Valve", Presentation of a mock early collaboration meeting with the FDA. Co-presenters included Thomas J. Callahan, Doyle Gantt, and Bette Lemperle of FDA's Division of Cardiovascular, Respiratory, and Neurological Devices. Presented to the Society for Biomaterials Annual Conference, San Diego, California, April 22, 1998
- "Regulatory Affairs: A 20th Century Profession" *Regulatory Affairs Focus*, Vol. 3, Issue 4, April 1998
- "New Canadian Regulations" Paper presented to the RAPS Annual Conference, Washington, D.C., September 8, 1997
- "Canadian Medical Device Proposal Includes New Requirements for Premarket Information", *Regulatory Affairs Focus*, Vol. 1, Issue 11, November 1996
- "Canada Proposing to Harmonize Medical Device Regulations", *Regulatory Affairs Focus*, Vol. 1, Issue 7, July 1996

Professional Organizations and Professional Certifications:

- Regulatory Affair Professional Society: Regulatory Affairs Certified (RAC)
- American Society for Quality: Certified Quality Auditor (CQA)